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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,072	01/02/2004	Sven Eyckerman	2676-6264US	2266

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EXAMINER	
HOWARD, ZACHARY C	
ART UNIT	**PAPER NUMBER**
1646	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/751,072	EYCKERMAN ET AL.	
	Examiner	Art Unit	
	Zachary C. Howard	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8,11,13,16 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-8,11,13,16 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 1/12/07 has been entered in full. Claims 1, 3-8, 11, 13, 16 and 22 are amended. Claims 2, 9, 10, 12, 14, 15 and 17-21 were previously canceled by Applicants.

Claims 1, 3-8, 11, 13, 16 and 22 are pending and under consideration.

Withdrawn Rejections

The following page numbers refer to the previous Office Action (10/10/06).

The rejection of claims 1, 3-8, 11, 13, 16 and 22 under 35 U.S.C. § 112, 2nd paragraph at pg 3 is *withdrawn* in view of Applicants' amendments to the claims.

The rejection of claims 1, 3-5, 11, 13, 16 and 22 under 35 U.S.C. § 102(b) at pg 3-6 as being clearly anticipated by Medici et al (1997) is *withdrawn* in view of Applicants' amendments to the claims.

The rejection of claims 6-8 under 35 U.S.C. § 103(a) at pg 6 as being unpatentable over Medici et al (1997) in view of Osborne et al (1995) is *withdrawn* in view of Applicants' amendments to the claims.

New Claim Rejections

Claim Rejections - 35 USC § 112, 1st paragraph, enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-8, 11, 13, 16 and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

(1) a recombinant receptor comprising an extracellular ligand-binding domain of a mammalian receptor; a LepRFFY cytoplasmic domain (a leptin receptor cytoplasmic domain with a phenylalanine residue at position 985; a phenylalanine residue at position

1077; and a tyrosine residue at position 1138); and a bait polypeptide heterologous to the leptin receptor cytoplasmic domain; wherein the activation of said recombinant receptor is inhibited by binding of a fusion protein to said bait polypeptide, said fusion protein comprising a prey polypeptide and an inhibitor of activation of said recombinant receptor that is the PTP-1B phosphatase domain; and

(2) a recombinant receptor comprising an extracellular ligand-binding domain of a mammalian receptor; a LepRFFY cytoplasmic domain (a leptin receptor cytoplasmic domain with a phenylalanine residue at position 985; a phenylalanine residue at position 1077; and a tyrosine residue at position 1138); and a bait polypeptide consisting of residues 370-453 of EpoR; wherein the activation of said recombinant receptor is inhibited by binding of a fusion protein to said heterologous bait polypeptide, said fusion protein comprising a CIS protein in which the SH2 domain of CIS (amino acids 82-218) is replaced with the SH2 domain of SOCS (amino acid residues 46-184);

(3) vectors and cells encoding said receptors;

does not reasonably provide enablement for

(1) a recombinant receptor comprising an extracellular ligand-binding domain of a mammalian receptor; a cytoplasmic domain comprising a domain derived from a cytoplasmic domain of a mammalian receptor, at least one activation site and a bait polypeptide heterologous to the domain derived from a cytoplasmic domain of a mammalian receptor; wherein the activation of said recombinant receptor is inhibited by binding of a fusion protein to said heterologous bait polypeptide, said fusion protein comprising a prey polypeptide and at least one of an inhibitor of the activation of said recombinant receptor and a recruitment site for the inhibitor of the activation of said recombinant receptor;

(2) vectors and cells encoding said receptor; or

(3) a recombinant transmembrane receptor, comprising a cytoplasmic domain comprising an intracellular domain derived from a mammalian receptor, a bait polypeptide and an activation site, wherein an interaction of a prey polypeptide with the bait polypeptide prevents the activation site from activating the recombinant transmembrane receptor; and an extracellular domain having a ligand binding domain

derived from a mammalian receptor, wherein binding of a ligand to the ligand binding domain activates the recombinant transmembrane receptor upon disruption of the interaction between the prey polypeptide and the bait polypeptide; and wherein the bait polypeptide is heterologous to the intracellular domain.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the invention is a recombinant receptor for use in screening for a molecule that disrupts an interaction between a bait and a prey molecule. The claimed receptor comprises a ligand-binding extracellular domain (ECD) from a mammalian receptor and a cytoplasmic domain with at least three parts: (1) a cytoplasmic domain from a mammalian receptor; (2) at least one activation site and (2) a heterologous bait polypeptide. The claims specify that activation of the receptor is inhibited by the binding of a prey molecule, or a fusion protein comprising a prey molecule, to the heterologous bait polypeptide. Claim 1 and dependent claims 3-8, 11, 13 and 16 require that said fusion protein comprises a prey polypeptide and either an inhibitor of the activation of the receptor or a recruitment site for the inhibitor of the activation the receptor. Claim 22 only requires a prey polypeptide that interacts with the activation site to inhibit activation of the recombinant transmembrane receptor. Claims 1, 3, 6-8, 11, 13, 16 and 22 broadly encompass a receptor (or a vectors or cell encoding a receptor) comprising an ECD from any type of receptor; a cytoplasmic domain from any type of receptor; and any form of bait and prey polypeptide wherein the prey polypeptide, or fusion protein comprising a prey polypeptide, binding inhibits receptor activation. Claims 4 and 5 limit

the receptor of claim 1 to a homomultimerizing (claim 4) or heteromultimerizing receptor (claim 5).

The invention provides limited teachings regarding the nature of the receptor from which the cytoplasmic domain is derived. The only specific receptor cytoplasmic domain that is disclosed in the specification is derived from the leptin receptor. The specification teaches "a homomultimerizing recombinant leptin receptor with a heterologous bait polypeptide fused into or, preferentially, at the carboxyterminal end of its cytoplasmic domain" (pg 5, ¶ [0014]). The specification does not teach any other specific receptor cytoplasmic domains that can be used in the claimed recombinant receptor. Furthermore, all of the working examples in the specification that are directed to a recombinant receptor encompassed by the claims include a very specific derivative of the cytoplasmic domain of the leptin receptor. This derivative is designated LepRFFY (see pg 18, ¶ [0079] and pg 22, ¶ [0093]) and includes a leptin receptor cytoplasmic domain with a phenylalanine residue at position 985; a phenylalanine residue at position 1077; and a tyrosine residue at position 1138. Example 1 (pg 22) describes the "specific inhibition of activation of the EpoR-LepRFFY-EpoR by the SOC3-CISSH2 chimera is disrupted by overexpression of SOCS2" (pg 22, ¶ [0093]). In the recombinant receptor used this example (EpoR-LepRFFY-EpoR), the first EpoR is the extracellular ligand-binding domain; the LepRFFY is the cytoplasmic domain from a receptor including an activation site (the 'Y' that is residue 1138 in native LepR) and the second EpoR is the bait molecule. The SOCS3-CISSH2 is a fusion protein consisting of a CIS protein in which the SH2 domain of CIS (amino acids 82-218) is replaced with the SH2 domain of SOCS (amino acid residues 46-184; see pg 20, ¶ [0084]). The CIS portion is the binding partner (prey) for the bait molecule (the second EpoR) and the SOCS3 SH2 domain is an inhibitor of activation of the receptor. As taught in Eyckerman et al (2005), the LepRFFY "contains a functional Y1138 STAT3 recruitment motif and is therefore signaling-competent, but it lacks the Y985 and Y1077 motifs required for recruitment of negative regulators" (pg 428 of Eyckerman et al, 2005. Nature Methods. 2(6): 427-433). Example 1 further teaches that the recombinant receptor shows "very strong inhibition upon co-transfection of the chimeric SOCS3 CISSH2 protein. The SH2 domain targets

the SOCS3 inhibitory regions towards the activated complex, resulting in specific inhibition" (pg 23, ¶ [00100]). Example 2 does not directly relate to the claimed receptor; instead it describes use of a recombinant receptor that is not encompassed by the claims to demonstrate that a specific bait-prey (ALK4-FKB12) interaction can be disrupted by the molecule FK506. In Example 3, ALK5 and FKB12 are used as bait and prey in the recombinant receptor and fusion protein from Example 1; in addition, a PTP-1B phosphatase domain is substituted for the inhibitory SOCS3 domain in the fusion protein. The specification further teaches that the inhibitor can be a "Suppressor of Cytokine Signalling (SOCS)" family member such as SOCS1 or SOCS3 (pg 7, ¶ [0018]). The specification further teaches that the inhibitor can be a "STAT phosphatase" or a "Protein Inhibitor of Activated STAT (PIAS), preferably PIAS3" (pg 7, ¶ [0019]).

In view of the teachings of the specification, the invention appears to be based on the following working model. Interaction between the bait molecule (found in the recombinant receptor) and the prey molecule (found in the fusion protein) allows the inhibitory molecule (also found in the fusion protein) to inhibit the activation site (1138Y) found in the cytoplasmic domain (also found in the recombinant receptor). This inhibition occurs even if a ligand (e.g., Epo) binds to an extracellular ligand-bind domain (e.g., EpoR) found the recombinant receptor. However, if a second molecule is added (in addition to the ligand) that disrupts the bait-prey interact, activation occurs because the inhibitory molecule is no longer recruited to the receptor to inhibit activation at the 1138Y residue (which functions as recruitment site for a STAT3 signaling molecule).

The specification does not provide any teachings regarding specific receptors other than the leptin receptor, or any activation sites found in other receptors, that can be used in the recombinant receptor of the invention. Even with regard to the leptin receptor, the specification does not teach the nature of any activation sites other than the tyrosine at residue 1138. The claims encompass a vast genus of receptor cytoplasmic domains, including receptors that are structurally unrelated to the leptin cytoplasmic domain of the invention, such as nuclear hormone receptors or G-protein coupled receptors (GPCRs). The leptin receptor is a type I cytokine receptor comprising a single transmembrane domain, whereas nuclear hormone receptors have no

transmembrane domains and GPCRs comprise multiple extracellular, transmembrane and cytoplasmic domains. The specification does not even provide any guidance as to which other type I cytokine receptors comprise cytoplasmic domains with activation sites that will work in the claimed invention.

Furthermore, while the instant specification suggests that a variety of inhibitors can be used in the fusion protein comprising a prey molecule and an inhibitor of activation, the relevant art teaches unpredictability as to which inhibitors will actually function as inhibitors when used with a recombinant receptor comprising the LepRFFY cytoplasmic domain and a specific bait-prey combination. The instant specification demonstrates use of a fusion protein comprising a CIS protein in which the SH2 domain of CIS (amino acids 82-218) is replaced with the SH2 domain of SOCS3 (amino acid residues 46-184). This fusion protein was used to inhibit a recombinant receptor comprising LepRFFY as the cytoplasmic domain and EpoR residues 370-453 as the bait molecule; the CIS prey molecule binds to the EpoR bait molecule and allows the SOCS3 domain to inhibit LepRFFY activation. In view of this result, the specification suggests that the SOCS3 domain can be used as an inhibitor with any recombinant receptor. However, the relevant art shows that when a different bait-prey combination is used (FKBP12 and ALK4), many potential inhibitors fail to work. Specifically, Eyckerman et al (2005; cited above) teaches, "we generated fusion constructs of both FKBP12 and ALK4 with a variety of inhibitory domains derived from SOCS molecules, tyrosine phosphatases and PIAS molecules. All efforts with SOCS-based i-prey constructs proved unsuccessful. Inhibition via the kinase inhibitory regions of SOCS-1 and SOCS-3 may require a very specific context or orientation of these domains. Fusion constructs with PIAS3 also did not have any inhibitory activity. In contrast, chimeric constructs containing the phosphatase domains of PTP-1B and TC-PTP (but not of SHP-1 or SHP-2) caused a substantial, specific reduction in signaling" (pg 429-430). Eyckerman further teaches that the phosphatase domain of PTP-1B works as inhibitor using a bait-prey combination that is MDM2-p53. However, another tyrosine phosphatase, TC-PTP, did not work with this combination of bait and prey. Therefore, the relevant art supports enablement for only a PTP-1B tyrosine phosphatase that will

work as an inhibitor of the LepRFFY cytoplasmic domain with a variety of different bait-prey combinations in conjunction.

The teaching of a single cytoplasmic domain as a working example of a cytoplasmic domain that can be used in the claimed receptor is not sufficient to enable the vast genus of potential cytoplasmic domains that are encompassed by the claimed receptor. The skilled artisan could not predict which cytoplasmic domains could be used in the claimed receptor to screen bait and prey molecules. Furthermore, the inhibitor molecules taught by the specification are all specific to a single activation domain (Y1138) found in the leptin receptor cytoplasmic domain, and the skilled artisan could not predict if any would work as inhibitors of other receptors. The skilled artisan would need to engage in experimentation to construct each potential recombinant receptor and fusion protein and screen the receptors to determine if the fusion protein acts as an inhibitor of the recombinant receptor. Such experimentation would be undue in view of the vast number of potential receptors and fusion proteins encompassed by the claims. Cytoplasmic domains other than the LepRFFY domain may or may not provide the required combination of characteristics. The skilled artisan would not be able to predict the nature of other leptin receptor cytoplasmic domains, or the nature of other receptors, that would function in the instant invention. Other receptors, even other cytokine receptors, are structurally discrete molecules from the leptin receptor, and the different structures may or may not be sufficient to allow an inhibitory molecule to inhibit an activation site on the receptor. Furthermore, the exact nature of the activation site on other receptors is not disclosed.

Due to the large quantity of experimentation necessary to generate the large number of recombinant receptors comprising receptor cytoplasmic domains, activation sites and bait molecules, and the corresponding fusion proteins comprising a prey molecule and an inhibitor of activation and screen the same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the

breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Rejections - 35 USC § 112, 1st paragraph, written description

Claims 1, 3-8, 11, 13, 16 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicants are claiming and what Applicants have possession of.

The claims are genus claims because the claims are directed to variant recombinant receptors, and vectors and cells encoding said variant receptors. Each genus is highly variant because a significant number of structural differences between genus members are permitted. In particular, claims 1, 3-8, 11, 13, 16 and 22 each encompass a receptor (or vector or cell encoding a receptor) comprising a cytoplasmic domain derived from any type of receptor and at least one activation site. As such, these claims encompass cytoplasmic domains from a vast array of structurally different receptors, including single transmembrane cytokine receptors as well as receptors without transmembrane domains (e.g., nuclear hormone receptors) or multiple transmembrane domains (e.g., G-protein coupled receptors).

From the specification, it is clear that Applicants have possession of a recombinant receptor comprising an extracellular ligand-binding domain of a mammalian receptor; a LepRFFY cytoplasmic domain (a leptin receptor cytoplasmic domain with a phenylalanine residue at position 985; a phenylalanine residue at position 1077; and a tyrosine residue at position 1138); and a heterologous bait polypeptide heterologous to the leptin receptor cytoplasmic domain; wherein the activation of said recombinant receptor is inhibited by binding of a fusion protein to said heterologous bait

polypeptide, said fusion protein comprising a prey polypeptide and an inhibitor of activation of said recombinant receptor that is the PTP-1B phosphatase domain. It is clear that Applicants have possession of a recombinant receptor comprising an extracellular ligand-binding domain of a mammalian receptor; a LepRFFY cytoplasmic domain (a leptin receptor cytoplasmic domain with a phenylalanine residue at position 985; a phenylalanine residue at position 1077; and a tyrosine residue at position 1138); and a heterologous bait polypeptide consisting of residues 370-453 of EpoR; wherein the activation of said recombinant receptor is inhibited by binding of a fusion protein to said heterologous bait polypeptide, said fusion protein comprising a CIS protein in which the SH2 domain of CIS (amino acids 82-218) is replaced with the SH2 domain of SOCS (amino acid residues 46-184).

However, the specification fails to describe or teach any other receptor cytoplasmic domain comprising a cytoplasmic domain, an activation site, and a heterologous bait polypeptide that will function in the instant invention.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure and function, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. In the instant case, the specification fails to provide sufficient descriptive information, such as definitive structural or functional features, or critical conserved regions, of the genus of recombinant receptors. There is not even identification of any particular portion of the structure of the cytoplasmic domain that must be conserved. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polypeptides, vectors and cells encompassed by the claims. Thus, no identifying characteristics or properties of the instant receptors are provided such that one of skill

would be able to predictably identify the encompassed molecules as being identical to those instantly claimed. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicants were not in possession of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed" (pg 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (pg 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGFs were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only:

(1) a recombinant receptor comprising an extracellular ligand-binding domain of a mammalian receptor; a LepRFFY cytoplasmic domain (a leptin receptor cytoplasmic domain with a phenylalanine residue at position 985; a phenylalanine residue at position 1077; and a tyrosine residue at position 1138); and a heterologous bait polypeptide heterologous to the leptin receptor cytoplasmic domain; wherein the activation of said recombinant receptor is inhibited by binding of a fusion protein to said heterologous bait

polypeptide, said fusion protein comprising a prey polypeptide and an inhibitor of activation of said recombinant receptor that is the PTP-1B phosphatase domain; and

(2) a recombinant receptor comprising an extracellular ligand-binding domain of a mammalian receptor; a LepRFFY cytoplasmic domain (a leptin receptor cytoplasmic domain with a phenylalanine residue at position 985; a phenylalanine residue at position 1077; and a tyrosine residue at position 1138); and a heterologous bait polypeptide consisting of residues 370-453 of EpoR; wherein the activation of said recombinant receptor is inhibited by binding of a fusion protein to said heterologous bait polypeptide, said fusion protein comprising a CIS protein in which the SH2 domain of CIS (amino acids 82-218) is replaced with the SH2 domain of SOCS (amino acid residues 46-184),

but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (pg 1115).

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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